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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/039,557 | 01/08/2002 | Teng-Kuei Yang | 12725 B | 1318 |

7590 04/20/2004

Hart, Baxley, Daniels & Holton
Fifth Floor
59 John Street
New York, NY 10038

EXAMINER

SHIAO, REI TSANG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1626

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/039,557 | | YANG ET AL. | |
| | Examiner | | Art Unit | |
| | Robert Shiao | | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 3/16, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment of claims 1 and cancellation of claims 2-14, and 16-19 in Paper No. 0304, dated March 16, 2004, is acknowledged. Claims 1 and 15 are pending in the application.

Reponses to Amendment

2. The rejection of claims 1 and 15 under 35 U.S.C. 112, first and second paragraph, has been overcome in Paper No. 0304, dated March 16, 2004. Since claims 13-14 and 16-19 have been cancelled, therefore, the rejection of claims 13-14 and 16-19 under 35 U.S.C. 112, first paragraph and second paragraph, is obviated. Since the non-elected subject matter which variables R^3 , R^4 , and N still form a 3-8-member heterocycle, therefore, the objection of claim 1 is maintained.

3. Applicant's arguments with respect to claims 1 and 15 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for variables R^3 , R^4 , and N still form a 3-8-member heterocycle. Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for variables R^3 , R^4 , and N still form a 3-8-member heterocycle, wherein heterocycle represents piperidine or pyrrolidinyl, does not reasonably provide enablement for variables R^3 , R^4 , and N still form a 3-8-member heterocycle, wherein said heterocycle represents morpholine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the limitation of 3-8-member heterocycle and morpholine in the invention commensurate in scope with these claims, see pages 1-9.

5. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine.

2) State of the prior art.

The reference Kang et al. CAS: 122:55341, does not indicate which compounds of instant formula I may be useful in the claimed invention. Kang et al. '55341 is pertaining to enantioselective addition of diethylzinc to aldehydes.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine, encompasses a vast number of compounds. Applicant's specification does not enable the public to prepare such a numerous amount of compounds of formula I by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The art is pertaining to related an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine, see claim 15, lines 2-3. Different types of the genus of formula I require various experimental procedures and without guidance that is applicable to all possible "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine", there would be little predictability in the scope of claimed compounds.

5) Amount of direction and guidance provided by the inventor.

The aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine, encompasses a vast number of compounds. Applicant's limited guidance does not enable the public to prepare such a numerous amount of "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle morpholine" in the specification. There is no enablement for "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine" representing general substituents including R^3 , R^4 , and N form azepane, pyrazine, etc., many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

The aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine, encompasses a vast number of compounds. Applicant's limited working examples do not enable the public to prepare such a numerous amount of "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine" in the specification. Applicants claim "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine", however, the specification provides limited examples of the instant compounds.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine".

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8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain "an aminothiols compound of formula I, wherein variables R^3 , R^4 , and N form a 3-8-member heterocycle or morpholine" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. A suggestion to obviate the rejection would be to incorporate the scope of "variables R^3 , R^4 , and N form a 3-8-member heterocycle (i.e., pyrrolidine)" into the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

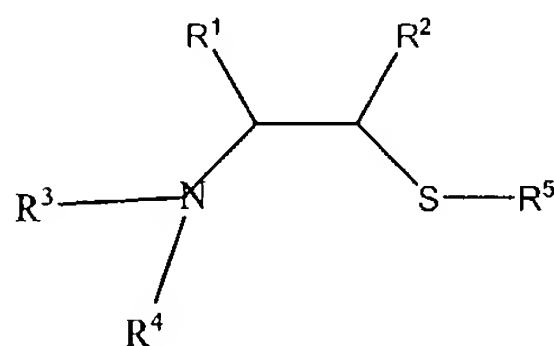
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al. publication, Synlett, 1994, 10:842-4, see CAS: 122:55341, and Bulletin of the Korean Chemical Society, 1996, 17(12), 1135-1142, see CAS: 126:131036; and

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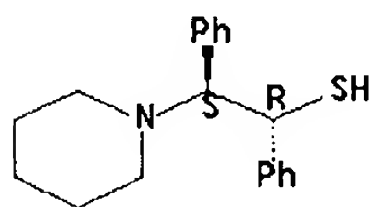
Carreno et al. publication, Organic Mass Spectrometry, 1990, 25(6), 339-42, see CAS: 113:131411.

Applicants claim a compound of formula (I),



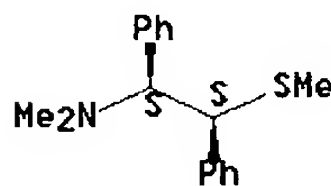
, and this compound is found in the pages 3-5 of the instant specification.

Kang et al. disclose a compound 1-Piperidineethanethiol, alpha, beta.-diphenyl-,



, which clearly anticipates the compound of formula (I), wherein the variables R¹ and R² independently represent aryl (i.e., phenyl); the variable R⁵ represents hydrogen; and R³, R⁴, and N form a 3-8-member heterocycle (i.e., piperidine), see RN:160011-80-3.

Carreno et al. disclose a compound Benzeneethanamine, N,N-dimethyl-.beta.-(methylthio)-.alpha.-phenyl-,



, which clearly anticipates the compound of formula (I), wherein the variables R¹ and R² independently represent aryl (i.e., phenyl); the variable R⁵ represents C₁₋₆ alkyl (i.e., methyl); and R³ and R⁴ independently represent C₁₋₉ alkyl (i.e., methyl), see RN:97241-47-9.

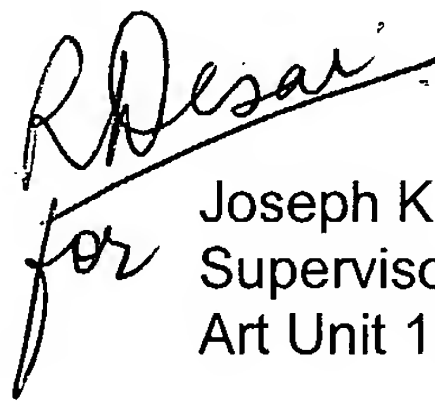
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Telephone Inquiry

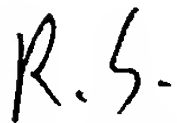
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "J. McKane", with a horizontal line drawn through it.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

A handwritten signature in black ink, appearing to read "R. Shiao".

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

April 16, 2004